DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2005

John M. Szabocsik, Ph.D.
SZABOCSIK AND ASSOCIATES
Suite 1200
203 North Wabash Avenue
Chicago, IL 60601

Re: K050517
Trade/Device Name: JSZ Multipurpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN
Dated (Date on orig SE ltr): February 18, 2005
Received (Date on orig SE Itr): March 1, 2005

Dear Dr. Szabocsik:

This letter corrects our substantially equivalent letter of April 13, 2005 regarding the trade name section of the reference block.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) NUMBER (IF KNOWN) K050517

Device Name: JSZ Multipurpose Solution

Indications for Use: The JSZ Multipurpose Solution is indicated for use in the daily cleaning, rinsing, chemical (not heat) disinfection, removal of proteins and storage of soft (hydrophilic) contact lenses as recommended by the eye care practitioner.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050517

Prescription Use ___ OR Over-The-Counter-Use ✓

(Per 21 CFR 801.109)
(Optional Format 1-2-96)

APR 1 3 2005

K050517

JSZ-Multipurpose Solution 510(k) FOI Summary

510(k) SUMMARY

JSZ-MULTIPURPOSE SOLUTION
FOR SOFT (HYDROPHILIC) CONTACT LENSES

This summary uses the format provided in 21 CFR 807.92:

(a)(1). **Submitter:**

John M. Szabocsik, PhD
President
SZABOCSIK AND ASSOCIATES INC
203 N WABASH AVE STE 1200
CHICAGO IL 60601

Phone 312-553-0828
FAX 312-553-0611

Summary prepared: February 18, 2005

(a)(2) **Device Trade Name:** JSZ-Multipurpose Solution

Device Common Name: Soft (hydrophilic) contact lens solution

Device Classification Name:
Accessories to Contact Lens Solution (86LPN)

(a)(3) **Identification of Predicate Device:**

This product is substantially equivalent to other currently marketed contact lens care multipurpose solutions.

(a)(4) **Device Description:**

The JSZ-Multipurpose Solution is a sterile, isotonic solution that contains poloxamer, sodium phosphate buffer, sodium chloride, and disodium edetate; preserved with polyhexanide 0.0001%. Contains no chlorhexidine or thimerosal.

This product is a clear, colorless solution packaged in plastic bottles with controlled dropper tips.

(a)(5) **Intended Use (Indications for Use):**

The JSZ Multipurpose Solution is indicated for use in the daily cleaning, rinsing, chemical (not heat) disinfection, removal of proteins and storage of soft (hydrophilic) contact lenses as recommended by the eye care practitioner.

JSZ-Multipurpose Solution 510(k) FOI Summary

(a)(6) **Comparison of Technological Characteristics:**

No changes have been made to the product formulation subject to this application.

b)(1) **Discussion of Nonclinical:**

I. Chemistry

A. Solution compatibility

The compatibility of the JSZ-Multipurpose Solution was demonstrated by cycling lenses through 30 cycles of simulated use, using the JSZ-Multipurpose Solution for cleaning, rinsing, disinfecting and storing. Parameters of lenses were measured before and after the 30 cycles, and no differences were found.

B. Cleaning effectiveness

The efficacy of the JSZ-Multipurpose Solution as a daily cleaner was shown by determining the critical micelle concentration.

II. Toxicology

The toxicological testing is summarized below, and reports are attached. The solution was shown to be non-toxic in all tests. Additional toxicity testing (cytotoxicity, systemic toxicity and ocular irritation) was done to verify the safety of the solution in the contract manufacturer's bottle.

A. Agar Overlay Cytotoxicity:

Representative lenses from all four groups of soft (hydrophilic) lens types were exposed to the JSZ-Multipurpose Solution for 24 hours, then tested in a direct contact cytotoxicity assay. All test lens types were noncytotoxic.

B. Systemic Toxicity:

The JSZ-Multipurpose Solution was evaluated for systemic toxicity by intraperitoneal (ip) injection in healthy mice, 50ml/kg body weight. The animals were observed over a 72 hour period, and showed no difference from control animals injected with saline. The solution passed the test requirements, that there be no difference between the response of test and control animals.

C. Acute Oral Toxicity

The JSZ-Multipurpose Solution was evaluated for acute oral toxicity by intubation in healthy rats, 5ml/kg body weight. The animals were observed immediately after intubation, after 2 and 4 hours, then daily for fourteen days. The animals were weighed prior to intubation, at 7 days, and at 14 days. All animals showed no clinical signs of toxicity from test initiation to Day 14, therefore the JSZ-Multipurpose Solution passed the test requirements of no acute oral toxicity.

D. Acute Ocular Irritation:

The JSZ-Multipurpose Solution was instilled directly into one eye of each of three rabbits, the other eye receiving sterile water as a control. Examinations over 72 hours showed no differences between test and control eyes, with no evidence of ocular irritation with either the test or control solutions. The JSZ-Multipurpose Solution therefore meets the requirements of the acute ocular irritation test, that it does not cause ocular irritation.

E. Full USP Class VI Testing of JSZ-Multipurpose Solution in bottles manufactured of PETROTHENE® LR 7320-01 high density polyethylene.

1. Cytotoxicity Test:

Under the conditions of this study, the SC test extract showed no evidence of causing cell lysis or toxicity. The negative controls, reagent controls, and the positive controls performed as anticipated. The SC test extract was not cytotoxic and passed this ISO study.

2. Systemic Toxicity Test:

Under the conditions of this study, there was no mortality or evidence of significant systemic toxicity from the extracts. Each test article extract met with USP requirements.

3. Ocular Irritation Study:

Under the conditions of this study, there was no evidence of significant irritation in the test or control eye of any rabbit. The SC and CSO test article extracts would not be considered irritants to the ocular tissue of the rabbits.

III. Microbiology

A. Sterility

Sterility data is included from the contract manufacturer.

B. Preservative efficacy

The JSZ-Multipurpose Solution solution passed the requirements of the preservative efficacy test.

C. Disinfection Efficacy

The JSZ-Multipurpose Solution passed the requirements of the stand-alone disinfection test, obviating the requirements for the multi-item testing.

D. Stability

Stability data is included from the contract manufacturer.

(b)(2) **Discussion of Clinical Data:**

A clinical trial of 6 months usage of the JSZ-Multipurpose Solution by 246 subjects, wearing representative lenses from all groups of soft (hydrophilic) contact lenses, compared to control groups using currently marketed care products, showed that the product is substantially equivalent to those current solutions.

(b)(3) **Conclusions Drawn from Data Supporting Equivalence Determinaation:**

In view of the In Vitro and clinical studies supporting the application, the safety, efficacy and comfort of the JSZ-Multipurpose Solution is substantially equivalent to other currently marketed contact lens care multipurpose solutions.